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IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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SHIRE ORPHAN THERAPIES LLC and) Civil Action
SANOFI-AVENTIS DEUTSCHLAND)
GMBH,)

Plaintiffs,)

v.)

FRESENIUS KABI USA, LLC,)

Defendant.)

No. 15-1102-GMS

- - -

Wilmington, Delaware
Tuesday, January 23, 2018
10:00 a.m.
Telephone Conference

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Senior Judge, U.S.D.C.,
District of Delaware

APPEARANCES:

JACK B. BLUMENFELD, ESQ., and
DAREN J. FAHNESTOCK, ESQ.
Morris, Nichols, Arsht & Tunnell LLP
-and-
EDGAR J. HAUG, ESQ.,
SANDRA KUZMICH, Ph.D., ESQ.,
LAURA A. CHUBB, ESQ., and
ELIZABETH MURPHY, ESQ.
Haug Partners LLP
(New York, NY)

Counsel for Plaintiffs

10:03:25 1 schedule.

10:03:27 2 This semester, I teach a course in patent

10:03:32 3 litigation at Duke, which I have taught basically every

10:03:35 4 other semester for a bit of time now.

10:03:38 5 We will work on -- I teach the course Thursday

10:03:41 6 evening -- we will work on Thursday morning from 9 to 11,

10:03:47 7 when I need to leave, get myself to the airport, and resume

10:03:53 8 the next day at 10:30, is my plan. My plane gets me there

10:04:02 9 in time to possibly get on the Bench by 10, but certainly by

10:04:05 10 10:30 barring any travel mishaps.

10:04:10 11 Let me find out, since you guys gave me some new

10:04:16 12 news this morning, I thought I would give you some, let's

10:04:20 13 find out how that will impact your planning and thinking. I

10:04:24 14 know you are just processing this. I know we set aside five

10:04:28 15 days. It seemed like a lot to me for a one-patent case.

10:04:32 16 Let's begin with plaintiff.

10:04:35 17 MR. BLUMENFELD: Your Honor, I don't think that

10:04:39 18 should be a problem. It sounds like we will have four days

10:04:44 19 plus a little more. We were hopeful of finishing the trial,

10:04:51 20 as Your Honor suggested, in a little less than five full

10:04:55 21 days anyway. We should be able to work around that and

10:04:59 22 still finish on Friday.

10:05:03 23 THE COURT: From defendant's point of view?

10:05:13 24 MR. JAMES: Your Honor, we agree with what Mr.

10:05:17 25 Blumenfeld just said, that we think there should be adequate

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1 APPEARANCES CONTINUED:

2 KAREN E. KELLER, ESQ.
Shaw Keller LLP

3 -and-

4 DARYL L. WIESEN, ESQ.

5 WILLIAM G. JAMES, ESQ.,

6 JOHN COY STULL, ESQ., and

7 SAMUEL SHERRY, ESQ.

8 Goodwin Procter LLP

(Washington, DC)

9 Counsel for Defendant

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10:02:30 9 THE COURT: Good morning, counsel. Who is on
10:02:32 10 the line for the plaintiffs this morning?

10:02:34 11 MR. BLUMENFELD: Good morning, Your Honor. It's

10:02:36 12 Jack Blumenfeld and Derek Fahnestock from Morris Nichols,
10:02:40 13 along with Ed Haug, Sandy Kuzmich, Liz Murphy, and Laura
10:02:46 14 Chubb from Haug Partners in New York.

10:02:48 15 THE COURT: Good morning.

10:02:50 16 For the defendant.

10:02:53 17 MS. KELLER: Good morning, Your Honor. Karen
10:02:55 18 Keller from Shaw Keller. With us today is Bill James, Daryl
10:03:00 19 Wiesen, Koy Stull, and Sam Sherry from Goodwin Procter.10:03:04 20 THE COURT: So if counsel, for the record, if
10:03:10 21 you would just let us all know who is speaking, since there
10:03:13 22 are multiple lawyers on the line for each party, that would
10:03:16 23 be helpful.

10:03:18 24 I don't think we have a ton to talk about today.

10:03:20 25 The first thing I need to mention is the

10:05:20 1 time in that schedule to finish the trial next week.

10:05:23 2 THE COURT: Great. Okay. Let's go to Exhibit

10:05:29 3 14. I got your letter.

10:05:32 4 MR. BLUMENFELD: Your Honor, just to fill you in

10:05:38 5 on Exhibit 14 and Exhibit 15, I think as a result of

10:05:45 6 conversations that the parties have had over the last few

10:05:51 7 days, we have resolved all of the issues in the cover order

10:05:56 8 and we have resolved most of the issues in Exhibit 14 and

10:06:01 9 15.

10:06:01 10 The only three evidentiary issues that I think

10:06:04 11 are left are the issue we raised about Dr. Raines, the issue

10:06:11 12 that the defendant raised about our expert, Ms. Ellis, and

10:06:18 13 an issue that the defendant raised in a letter to Your Honor

10:06:23 14 last night.

10:06:27 15 We are also to happy to just take them up at

10:06:30 16 trial since they are all kind of witness issues, whichever

10:06:34 17 Your Honor would prefer.

10:06:36 18 THE COURT: How does the other side feel?

10:06:41 19 MR. JAMES: Your Honor, I will jump in. I think

10:06:48 20 Mr. Wiesen will handle the issue about from Dr. Raines and

10:06:51 21 Ms. Ellis.

10:06:52 22 If I could talk about the other issue we sent

10:06:57 23 Your Honor last night by letter, so we were trying to give

10:07:00 24 you the opportunity to look at the issue before the call.

10:07:07 25 It relates to the schedule. As you know, yesterday, you

10:07:11 **1** entered an order in which we dropped our Section 103
 10:07:18 **2** obviousness case. The only two defenses remaining are
 10:07:22 **3** obvious type double patenting and laches. In that regard,
 10:07:26 **4** the plaintiffs have submitted expert reports from Dr. Bell,
 10:07:32 **5** who is an economist, and Dr. Kaplan, who is a clinician,
 10:07:37 **6** related to secondary considerations.
 10:07:41 **7** Dr. Bell talks about obviousness in his expert
 10:07:44 **8** report, sort of lies the predicate, legal and economic
 10:07:50 **9** framework for why we care about commercial success. He
 10:07:54 **10** doesn't say anything about obviousness double type
 10:07:59 **11** patenting. He doesn't reference the ODP, the obvious type
 10:08:06 **12** double-patenting reference patents we are relying on.
 10:08:10 **13** THE COURT: This is which witness?
 10:08:13 **14** MR. JAMES: Dr. Bell. The economist.
 10:08:21 **15** Dr. Kaplan also, he doesn't talk about
 10:08:25 **16** obviousness type double patenting or obviousness, for that
 10:08:29 **17** matter. He doesn't talk about the reference patent, the
 10:08:33 **18** 7803 patent we are calling it in this case.
 10:08:38 **19** Your Honor, we didn't have notice under Rule 26
 10:08:40 **20** about these opinions relating to the obviousness type double
 10:08:45 **21** patenting argument. We couldn't have our experts respond to
 10:08:50 **22** whatever assertions they might make about why these things
 10:08:54 **23** are relevant. We couldn't take their depositions because
 10:08:57 **24** they weren't in their expert reports.
 10:08:59 **25** We don't think they should be testifying at

10:09:02 **1** trial on the obviousness type double patenting defense. By
 10:09:08 **2** the same token, if they do not put in evidence on commercial
 10:09:13 **3** success through Dr. Bell, their economist, and Dr. Kaplan,
 10:09:16 **4** their clinician, we wouldn't put in our counterpart, Dr.
 10:09:19 **5** Hofmann, our economist and Dr. Pines, a clinician.
 10:09:23 **6** THE COURT: So it's a notice issue.
 10:09:27 **7** MR. JAMES: It is.
 10:09:29 **8** THE COURT: Could I hear a response, please.
 10:09:32 **9** MR. BLUMENFELD: Your Honor, it is really not a
 10:09:34 **10** notice issue. They had full notice of everything that Dr.
 10:09:38 **11** Bell and Dr. Kaplan were going to talk about. Dr. Bell is
 10:09:42 **12** an economist. Dr. Kaplan is a physician, a doctor.
 10:09:47 **13** When their reports were done, they didn't talk
 10:09:50 **14** about obviousness or about obviousness type double
 10:09:54 **15** patenting. They talked about the commercial success in Dr.
 10:10:01 **16** Bell's case, about the long-felt need for the drug in Dr.
 10:10:05 **17** Kaplan's case.
 10:10:07 **18** At that time, obviousness was in the case,
 10:10:12 **19** obviousness type double patenting wasn't even in the case at
 10:10:16 **20** that time. In its findings and conclusions, which are Tab
 10:10:19 **21** 13 of the pretrial order, Fresenius incorporates its
 10:10:24 **22** obviousness section by reference in obviousness type double
 10:10:30 **23** patenting. They say that Claim 14, which is the only claim
 10:10:34 **24** at issue anymore, is an obvious variant based on the prior
 10:10:39 **25** art.

10:10:40 **1** We relied on secondary considerations, long-felt
 10:10:43 **2** need and commercial success. This is a little bit of a --
 10:10:47 **3** it feels like a little bit of a trick here.
 10:10:51 **4** Yesterday Fresenius dropped obviousness, then
 10:10:54 **5** last night they say, okay, now you can't put in your
 10:10:57 **6** secondary considerations. Although secondary considerations
 10:11:03 **7** went to both obviousness and obviousness type double
 10:11:07 **8** patenting, and they don't change and the discovery doesn't
 10:11:09 **9** change, the reports don't change, the depositions don't
 10:11:12 **10** change, depending on whether it goes to obviousness or
 10:11:16 **11** obviousness type double patenting.
 10:11:18 **12** On the legal point, it's clear that secondary
 10:11:20 **13** considerations, like commercial success and long-felt need,
 10:11:26 **14** are relevant and are as relevant to obviousness type double
 10:11:31 **15** patenting as to obviousness. Your Honor had this issue in
 10:11:33 **16** the Eli Lilly v. Teva case back in 2011 or 2012 where you
 10:11:40 **17** excluded evidence of secondary considerations going to
 10:11:45 **18** obviousness type double patenting because of a footnote in a
 10:11:50 **19** Federal Circuit case, the Geneva, said that was erroneous,
 10:11:58 **20** they affirmed your opinion but said your secondary
 10:12:03 **21** consideration evidence was erroneous.
 10:12:05 **22** More recently, in UCB v. Accord in 2016, Judge
 10:12:11 **23** Stark said, and I will quote his opinion, 201 F.Supp. 3rd.
 10:12:16 **24** 491 at 536, "Generally, when considering whether a patent is
 10:12:21 **25** invalid for obviousness type double patenting, the Court is

10:12:24 **1** required to considered objective indicators of
 10:12:28 **2** nonobviousness of such evidence if presented."
 10:12:33 **3** We have presented it. It doesn't change because
 10:12:37 **4** they dropped obviousness and are only asserting obviousness
 10:12:41 **5** type double patenting.
 10:12:42 **6** It is the same evidence we presented in our
 10:12:45 **7** report and the depositions. Nothing about it changes.
 10:12:49 **8** THE COURT: I will hear a brief response.
 10:12:53 **9** MR. JAMES: Your Honor, Mr. Blumenfeld is right
 10:12:56 **10** that the Federal Circuit said that secondary considerations
 10:13:00 **11** can be relevant in obviousness type double patenting
 10:13:04 **12** contexts. But you have to demonstrate how they are
 10:13:11 **13** relevant. So here we are not arguing obviousness over the
 10:13:15 **14** prior art per se.
 10:13:16 **15** There is a patent that is owned by Hoechst that
 10:13:21 **16** claims an intermediate to the compound that is claimed in
 10:13:24 **17** this litigation, and there is no effort made by the
 10:13:31 **18** economist or the clinician, doctor/clinician, to demonstrate
 10:13:36 **19** how either one of their factors would be relevant in that
 10:13:40 **20** context.
 10:13:41 **21** So, yes, it can be relevant, but it has to be
 10:13:45 **22** demonstrated how it's relevant in the particular
 10:13:47 **23** circumstances. None of that is in the expert report.
 10:13:52 **24** Again, it is not even mentioned. We didn't have the
 10:13:55 **25** opportunity to vet that in discovery.

10:13:58 **1** We are not saying that it's per se out in an ODP
 10:14:03 **2** context, that is not right. We understand secondary
 10:14:07 **3** considerations can be relevant. But we weren't on notice as
 10:14:10 **4** to how they were going to try to prove that up.
 10:14:12 **5** THE COURT: Okay.
 10:14:13 **6** Mr. Blumenfeld.
 10:14:14 **7** MR. BLUMENFELD: Your Honor, I really don't
 10:14:17 **8** understand that point, because the issue here is whether
 10:14:23 **9** there are secondary considerations that apply to Claim 14.
 10:14:28 **10** Their claim is that Claim 14 is an obvious variant based on
 10:14:36 **11** a certain reference and based on other prior art which they
 10:14:40 **12** were till yesterday also relying on for obviousness.
 10:14:43 **13** It doesn't change the analysis to say the
 10:14:47 **14** invention of Claim 14 was a commercial success, the
 10:14:51 **15** invention of Claim 14 satisfied a long-felt need, to say
 10:14:56 **16** that somehow that is different if it is a double patenting
 10:14:59 **17** obviousness analysis or a straight obviousness analysis.
 10:15:05 **18** A couple weeks ago, when Your Honor permitted
 10:15:08 **19** double patenting to come into the case, Fresenius told you
 10:15:12 **20** that all of the discovery that was needed was done. So now
 10:15:17 **21** to hear that somehow something wasn't done is a little
 10:15:22 **22** surprising to us.
 10:15:24 **23** Nothing changes. The only thing I heard was
 10:15:27 **24** that they didn't tell us that these same facts that they are
 10:15:31 **25** relying on for commercial success and for long-felt need now

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10:15:35 **1** apply to whether Claim 14 is an obvious variant as opposed
 10:15:40 **2** to whether Claim 14 was obvious under a straight 103
 10:15:45 **3** analysis. There is nothing different about it.
 10:15:48 **4** THE COURT: Last word, counsel.
 10:15:51 **5** MR. JAMES: Your Honor, if I could.
 10:15:54 **6** It makes all the difference in the world whether
 10:15:56 **7** we are talking about obviousness over the prior art which
 10:16:00 **8** arose prior to 1989 or over this intermediate claimed in a
 10:16:06 **9** patent owned by the plaintiffs that arose in 1997 and how
 10:16:12 **10** there is any relevance of the commercial success of the
 10:16:17 **11** product ultimately over that compound.
 10:16:20 **12** The relevance of these two, the long-felt need
 10:16:24 **13** and the commercial success, makes all the relevance in the
 10:16:28 **14** world which defense we are talking about.
 10:16:31 **15** On the discovery point, I did tell you that
 10:16:34 **16** discovery had been completed. And that was because their
 10:16:38 **17** other experts addressed the obviousness type double
 10:16:41 **18** patenting argument and we took their depositions on it.
 10:16:44 **19** That just didn't occur with respect to these two experts.
 10:16:48 **20** We had no notice that these opinions were relevant to the
 10:16:51 **21** ODP argument.
 10:16:54 **22** THE COURT: Is that a reasonable statement for
 10:16:59 **23** your colleague to make, Mr. Blumenfeld, under the
 10:17:01 **24** circumstances?
 10:17:03 **25** MR. BLUMENFELD: I am sorry, I don't think that

10:17:06 **1** was a reasonable statement at all. The question in either
 10:17:11 **2** case, whether it is obviousness or obviousness type double
 10:17:15 **3** patenting, was whether the invention was obvious at the time
 10:17:19 **4** of the invention. The questions about secondary
 10:17:25 **5** considerations go to exactly the same thing, whether for 103
 10:17:29 **6** or for double patenting it was obvious at the time of the
 10:17:34 **7** invention. The commercial success and long-felt need are
 10:17:38 **8** the same, exactly the same in either case.
 10:17:40 **9** THE COURT: Counsel for defense, Mr. James, I
 10:17:51 **10** can't see how it would be prudent for the trial judge, for
 10:17:55 **11** me, at this juncture, to exclude this evidence, given what I
 10:18:03 **12** have just heard. Why wouldn't it make more sense to go
 10:18:07 **13** ahead and listen to the evidence and give counsel a chance
 10:18:10 **14** to renew your discussion either during the trial, perhaps at
 10:18:16 **15** two different times, after the witnesses have testified
 10:18:20 **16** and/or posttrial? Why risk having to do this again by
 10:18:28 **17** having me perhaps prematurely preclude the witnesses? The
 10:18:36 **18** record will be more fulsomely developed and I will have a
 10:18:40 **19** more clear picture than I frankly do today, given the
 10:18:45 **20** limited opportunity I have had to understand the issue and
 10:18:48 **21** its relatively late presentation to the Court.
 10:18:52 **22** Can you tell me why it would be prudent for me
 10:18:55 **23** to act now rather than later?
 10:18:58 **24** MR. JAMES: Your Honor, I understand your
 10:19:00 **25** concern. Certainly, we will renew whatever objections we

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10:19:07 **1** have during their testimony and after, in the posttrial
 10:19:10 **2** briefs, if that is Your Honor's ruling. But I don't think
 10:19:13 **3** you have heard today anything from counsel for the
 10:19:16 **4** plaintiffs about how obvious type double patenting was
 10:19:23 **5** referenced in these expert reports.
 10:19:25 **6** THE COURT: I understand your point, Mr. James.
 10:19:29 **7** Do you want to respond to that, Mr. Blumenfeld? You didn't
 10:19:31 **8** use the magic words, I guess, is sort of what I am hearing.
 10:19:35 **9** MR. BLUMENFELD: Yes, Your Honor. Those reports
 10:19:38 **10** didn't use the terms obviousness type double patenting.
 10:19:43 **11** They used the term obviousness. At that time obviousness
 10:19:47 **12** was the defense that was pleaded. But they don't analyze
 10:19:53 **13** the prior art. They don't discuss either of them. They
 10:19:56 **14** don't discuss the prior art. They talk about the invention,
 10:19:59 **15** the invention of the '333 patent, the patent in suit, is the
 10:20:03 **16** same for both.
 10:20:05 **17** The analysis of commercial success is the same
 10:20:10 **18** for both. These weren't experts that were coming in and
 10:20:12 **19** saying let me tell you about the prior art. That has
 10:20:16 **20** nothing to do with their testimony.
 10:20:17 **21** THE COURT: That's what I thought I heard, Mr.
 10:20:20 **22** James. I am going to deny your motion, without prejudice to
 10:20:23 **23** your renewing your argument as I said earlier.
 10:20:27 **24** MR. JAMES: I understand.
 10:20:29 **25** THE COURT: We have No. 1, for this Dr. Raines,

10:20:40 **1** that I think the plaintiff complains is a witness I
 10:20:44 **2** shouldn't hear regarding prosecution history. Is that
 10:20:48 **3** correct, Mr. Blumenfeld?
 10:20:49 **4** **MR. BLUMENFELD:** It is, Your Honor. Ms. Ellis
 10:20:51 **5** is the other side of that. These are two experts, one a
 10:20:57 **6** scientist on their side, a patent person on our side. The
 10:21:02 **7** question is whether either of them should be permitted to
 10:21:09 **8** testify about the prosecution history. Different reasons by
 10:21:14 **9** the different parties as to why they think they shouldn't.
 10:21:20 **10** Again, I leave it to Your Honor whether you
 10:21:22 **11** think it makes more sense to deal with it now or deal with
 10:21:26 **12** it at trial when you have context for both of these
 10:21:30 **13** witnesses, who they are and what they are saying. If you do
 10:21:34 **14** want to hear about it, Mr. Haug is prepared to talk about
 10:21:39 **15** both of them. I leave it to you.
 10:21:40 **16** **THE COURT:** I am willing to wait if the parties
 10:21:43 **17** would prefer. I think you know, and I think Ms. Keller
 10:21:49 **18** knows, I wouldn't typically be inclined to hear from
 10:21:53 **19** witnesses of this type.
 10:21:55 **20** **MR. BLUMENFELD:** Your Honor, these are not
 10:21:58 **21** witnesses, I think on either side, who are going to come in
 10:22:01 **22** and say, at least on our side, I will talk about our expert,
 10:22:06 **23** the patent is not unenforceable because there is a
 10:22:12 **24** prosecution laches defense and what Ms. Ellis would do is go
 10:22:17 **25** through the file history to explain what happened during

10:22:21 **1** file history. That's why we are offering her.
 10:22:26 **2** Again, I leave it to you whether you want to
 10:22:30 **3** hear about that on both sides today or in trial where there
 10:22:36 **4** is some context for what the issue is.
 10:22:38 **5** **THE COURT:** Let's hear the other perspective.
 10:22:43 **6** **MR. WIESEN:** Your Honor, on behalf of Fresenius
 10:22:46 **7** on these two issues.
 10:22:48 **8** I agree with Mr. Blumenfeld that these are in
 10:22:52 **9** some ways two sides of the same coin and they respond to
 10:22:56 **10** each other. I think the two parties have taken a different
 10:22:59 **11** approach to how to what expert is appropriate to provide
 10:23:03 **12** analysis for the Court on the prosecution history related to
 10:23:06 **13** the prosecution laches issue.
 10:23:09 **14** Dr. Raines is a peptide chemist. He is not a
 10:23:12 **15** patent lawyer. And the subject matter of his testimony is
 10:23:16 **16** to run through the scientific issues related to the
 10:23:21 **17** prosecution history, to discuss scientifically what the
 10:23:25 **18** Patent Office was asking for the information that Shire or
 10:23:30 **19** its predecessor Hopes Kab (phonetic) at the time, and when
 10:23:34 **20** they could have provided a scientific response certainly
 10:23:38 **21** sets the context for that with the prosecution history. He
 10:23:41 **22** can't do that scientific analysis without looking at what
 10:23:44 **23** the examiner is asking for. But fundamentally his testimony
 10:23:48 **24** is not about the prosecution history but is about the
 10:23:52 **25** science related to the prosecution history.

10:23:55 **1** We don't intend to have him present opinions
 10:23:58 **2** about Patent Office office procedure but rather about the
 10:24:02 **3** scientific that have been run by Shire.
 10:24:08 **4** Dr. Ellis --
 10:24:10 **5** **THE COURT:** That strikes me as different. I am
 10:24:12 **6** agreeing with you.
 10:24:14 **7** **MR. WIESEN:** Dr. Ellis, on the other hand, is a
 10:24:17 **8** more classic patent law expert. She has spent her career
 10:24:21 **9** working at the Patent Office and then prosecuting patents.
 10:24:23 **10** While she does have a Ph.D., they didn't ask her to do any
 10:24:27 **11** technical analysis. And she fundamentally runs through the
 10:24:31 **12** prosecution history and says this is consistent with this
 10:24:36 **13** rule, this is allowed because of this rule, this timing is
 10:24:39 **14** allowed to just file a continuation application rather than
 10:24:42 **15** provide a substantive response.
 10:24:44 **16** We think there is really two reasons action that
 10:24:46 **17** Dr. Ellis need not testify. The first is what Your Honor
 10:24:50 **18** referred to, which is that we can read the prosecution
 10:24:55 **19** history here. With a jury trial maybe it would be
 10:24:59 **20** different. With a Bench trial, I don't think there is
 10:25:02 **21** anything too complicated.
 10:25:03 **22** The second issue is whether it is even really
 10:25:06 **23** particularly relevant to the prosecution laches issue. If
 10:25:10 **24** you look at the case where the Federal Circuit sort of
 10:25:15 **25** brought this doctrine back to the forefront about 15 years

10:25:18 **1** ago, the Symbol Technologies v. Lemelson case, the way they
 10:25:22 **2** ask the question is whether, even though the patentee
 10:25:25 **3** complied with the Patent Office procedures, if they delayed
 10:25:28 **4** too much without an explanation is laches appropriate.
 10:25:31 **5** So having Dr. Ellis show up and explain that
 10:25:34 **6** they complied with the Patent Office procedures is
 10:25:36 **7** irrelevant. I don't think it's even really disputed. We
 10:25:41 **8** are not contesting they didn't comply with the strict orders
 10:25:44 **9** of the MPEP and file continuations when they were legally
 10:25:49 **10** available.
 10:25:51 **11** The argument is despite following those rules,
 10:25:54 **12** Symbol Technologies sayings prosecution laches is available
 10:25:57 **13** as a defense. That is what our argument is here.
 10:26:00 **14** **MR. BLUMENFELD:** Your Honor, I will defer to Mr.
 10:26:03 **15** Haug.
 10:26:03 **16** **THE COURT:** You did say that.
 10:26:04 **17** **MR. HAUG:** No problem. This is Ed Haug.
 10:26:11 **18** With respect to first Dr. Ellis, we are not
 10:26:14 **19** offering Dr. Ellis as a patent attorney to talk about patent
 10:26:18 **20** law. She has been offered based on her expertise and as an
 10:26:24 **21** expert Patent Office practice and procedures. I think those
 10:26:29 **22** issues are important in this particular case. We are
 10:26:32 **23** talking about pre-GATT prosecution. We are also talking
 10:26:36 **24** about utilities guidelines that were used by the Patent
 10:26:39 **25** Office that are relevant here. She speaks about that, which

10:26:41 **1** we think would be helpful to the Court to appreciate the
 10:26:46 **2** context of the prosecution here.
 10:26:48 **3** We are not offering Dr. Ellis to talk about the
 10:26:51 **4** core legal issues of the prosecution and delay or no delay.
 10:26:56 **5** And also Dr. Ellis was in the Patent Office for
 10:27:00 **6** about 20 years, including during the relevant time period of
 10:27:05 **7** the prosecution here, and also in the art group that this
 10:27:09 **8** application was prosecution in, which is the biotechnology
 10:27:13 **9** group.
 10:27:13 **10** We think for all those reasons she would be
 10:27:16 **11** helpful to the Court to help the Court better understand the
 10:27:21 **12** prosecution to the extent Your Honor needs that help.
 10:27:24 **13** That is our view on Dr. Ellis.
 10:27:26 **14** I think it's r. Raines, it's different, because
 10:27:31 **15** he is a scientist and has no experience in Patent Office
 10:27:35 **16** practice. And his report put in in this case, which is very
 10:27:38 **17** lengthy, doesn't in fact walk through the prosecution. That
 10:27:41 **18** is the primary reason why we objected.
 10:27:43 **19** I just heard Mr. Wiesen say maybe he is not
 10:27:47 **20** going to offer him to do that and he is going to be limited
 10:27:51 **21** to some scientific opinions which may not be so
 10:27:55 **22** objectionable if objectionable at all. We won't know that
 10:27:58 **23** until trial.
 10:28:00 **24** THE COURT: Let's start there then and gets get
 10:28:03 **25** Mr. Wiesen to react. I think you are right, Mr. Haug. That

10:28:07 **1** is what I heard as well.
 10:28:10 **2** MR. WIESEN: Your Honor, I think that's right
 10:28:12 **3** with the caveat that, without preferring to the prosecution
 10:28:15 **4** Dr. Raines can't talk about the scientific issues. In other
 10:28:19 **5** words, what we will see in the prosecution history is that
 10:28:23 **6** the examiner was asking for certain kinds of data. We do
 10:28:26 **7** intend to have Dr. Raines talk about the prosecution history
 10:28:30 **8** just to the extent he points out that was the type of data
 10:28:34 **9** that was being requested that talks about the scientific
 10:28:36 **10** issues about what that data is and what was available.
 10:28:40 **11** So the prosecution history certainly will come
 10:28:42 **12** up to set the frame and context.
 10:28:45 **13** THE COURT: Mr. Haug, with that proviso, would
 10:28:49 **14** you object?
 10:28:50 **15** MR. HAUG: I may not with that proviso, if I
 10:28:56 **16** fully understand it, which I am not sure I will until I hear
 10:28:59 **17** it.
 10:29:00 **18** THE COURT: We can do some realtime work as
 10:29:03 **19** well. I think maybe this witness in your view may be less
 10:29:07 **20** problematic than you originally thought, perhaps.
 10:29:15 **21** MR. HAUG: Perhaps. I can't predict.
 10:29:18 **22** THE COURT: Okay. Go ahead, Mr. Wiesen.
 10:29:25 **23** MR. WIESEN: That was all I had on Dr. Raines.
 10:29:29 **24** Dr. Ellis, I think what we heard from Mr. Haug
 10:29:33 **25** is really that she is going to run through some of the legal

10:29:37 **1** issues, what happens with a pre-GATT versus a post-GATT
 10:29:44 **2** patent and when they expire and how the expiration dates are
 10:29:47 **3** calculated, some guidelines that they are certainly entitled
 10:29:50 **4** to cite and argue from, but that I don't think we need a
 10:29:53 **5** witness to explain.
 10:29:55 **6** Then running through the prosecution history,
 10:29:57 **7** which, again, I think, although it's somewhat lengthy, can
 10:30:02 **8** be done without a witness.
 10:30:04 **9** THE COURT: Mr. Haug, I tend to not want to
 10:30:10 **10** spend time doing things from the stand, the witness box, we
 10:30:15 **11** don't need to spend time doing.
 10:30:18 **12** With that in mind, I will let the witness take
 10:30:22 **13** the stand, but I think you should tailor their testimony
 10:30:26 **14** accordingly.
 10:30:27 **15** MR. HAUG: Absolutely. Thank you, Your Honor.
 10:30:30 **16** THE COURT: The same with regard to Dr. Raines,
 10:30:32 **17** Mr. Wiesen.
 10:30:33 **18** MR. WIESEN: Absolutely, Your Honor. Thank you.
 10:30:36 **19** THE COURT: Okay. What do we have left now?
 10:30:40 **20** MR. BLUMENFELD: Your Honor, I don't think we
 10:30:42 **21** have anything else. The issues that were raised in the body
 10:30:45 **22** of the pretrial order, the parties have resolved. I guess
 10:30:49 **23** that just leaves the question for us whether you want us to
 10:30:53 **24** submit a new cover order that reflects those agreements or
 10:31:01 **25** whether the agreements we have are sufficient for your

10:31:04 **1** purposes.
 10:31:04 **2** THE COURT: I think they are sufficient, unless
 10:31:06 **3** counsel feel more comfortable spending the time to submit an
 10:31:12 **4** additional order. I am comfortable, if the parties are.
 10:31:16 **5** MR. BLUMENFELD: Certainly the plaintiffs are.
 10:31:18 **6** We think we know what the agreements are.
 10:31:20 **7** THE COURT: Mr. Wiesen.
 10:31:22 **8** MR. JAMES: Your Honor, I would we would be
 10:31:26 **9** comfortable with that as well. We know what the two or
 10:31:29 **10** three issues were. We know what the agreement was.
 10:31:32 **11** THE COURT: Then that's all I need to hear.
 10:31:36 **12** Anything else then, counsel?
 10:31:40 **13** MR. HAUG: Your Honor, a question. Your
 10:31:42 **14** preference for opening statements and length, if at all?
 10:31:46 **15** THE COURT: I do invite openings with emphasis
 10:31:52 **16** on brevity. There is inevitably going to be some degree of
 10:31:58 **17** repetition. I would like the parties to keep it down to a
 10:32:04 **18** dull roar if you could. After a point, I will get it. I
 10:32:11 **19** don't anticipate wanting to entertain closings at this
 10:32:16 **20** juncture. I usually don't.
 10:32:18 **21** It's not unheard of that I have asked. If I do,
 10:32:21 **22** I expect good lawyers to get on their feet and even when not
 10:32:27 **23** completely prepared to respond to Court's questions. But at
 10:32:31 **24** this juncture, I am not asking you to prepare a formal
 10:32:35 **25** closings.

10:32:38 **1** MR. JAMES: Thank you, Your Honor.

10:32:40 **2** MR. WIESEN: Your Honor, as a followup to Mr.

10:32:42 **3** Haug's comment.

10:32:44 **4** To flag it, I think we put in the pretrial order

10:32:47 **5** that the parties have agreed, since it's an invalidity and

10:32:50 **6** unenforceability case, that defendants are going to go

10:32:53 **7** first. So you are not surprised by that on Monday, I wanted

10:33:00 **8** to flag that. Although there is, partially due to some

10:33:04 **9** witness availability as well, the expectation is that we

10:33:07 **10** will go first on substantive issues, the defendants will

10:33:11 **11** rebut, and then the plaintiffs will reply with witnesses on

10:33:14 **12** secondary considerations that we have discussed.

10:33:18 **13** THE COURT: That is fine. It's almost 20 years,

10:33:21 **14** Mr. Wiesen. Tough to find something new under the sun.

10:33:26 **15** MR. WIESEN: Understood, Your Honor.

10:33:28 **16** THE COURT: Anything else, counsel?

10:33:29 **17** MR. JAMES: Your Honor, we do have one witness,

10:33:37 **18** Dr. Pines, a clinician, who will be testifying now. As a

10:33:44 **19** busy physician, he has some scheduling issues. He can't

10:33:49 **20** testify on Wednesday. He can testify on Tuesday or

10:33:54 **21** Thursday. I don't know about Friday. I don't think he is

10:33:58 **22** available then, either.

10:33:59 **23** We will work with the other side to try to make

10:34:02 **24** sure that doesn't impact the schedule otherwise.

10:34:04 **25** THE COURT: If the parties are comfortable with

10:34:06 **1** taking a witness out of turn, if that is the case, if that

10:34:10 **2** is what you are suggesting needs to be done, Mr. James, I am

10:34:13 **3** fine. If there is an objection, obviously, I have to take

10:34:17 **4** it up. I am comfortable with you working that out on your

10:34:20 **5** own.

10:34:21 **6** MR. HAUG: Your Honor, we have already agreed to

10:34:24 **7** allow the witness to go out of turn for his convenience.

10:34:28 **8** That is not an issue.

10:34:31 **9** THE COURT: Okay.

10:34:31 **10** Mr. James, does that satisfy you?

10:34:34 **11** MR. JAMES: Your Honor.

10:34:35 **12** THE COURT: Okay. Unless there is anything

10:34:39 **13** else, have a good week, counsel. Take care.

14 (Conference concluded at 10:35 a.m.)

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'333 [1] - 12:15	accord [1] - 7:22 accordingly [1] - 19:14 act [1] - 11:23 action [1] - 15:16 Action [1] - 1:4 additional [1] - 20:4 addressed [1] - 10:17 adequate [1] - 3:25 affirmed [1] - 7:20 ago [2] - 9:18, 16:1 agree [2] - 3:24, 14:8 agreed [2] - 21:5, 22:6 agreeing [1] - 15:6 agreement [1] - 20:10 agreements [3] - 19:24, 19:25, 20:6 ahead [2] - 11:13, 18:22 airport [1] - 3:7 allow [1] - 22:7 allowed [2] - 15:13, 15:14 almost [1] - 21:13 analysis [8] - 9:13, 9:17, 10:3, 12:17, 14:12, 14:22, 15:11 analyze [1] - 12:12 AND [1] - 1:2 anticipate [1] - 20:19 anyway [1] - 3:21 APPEARANCES [2] - 1:16, 2:1 application [2] - 15:14, 17:8 apply [2] - 9:9, 10:1 appreciate [1] - 17:1 approach [1] - 14:11 appropriate [2] - 14:11, 16:4 argue [1] - 19:4 arguing [1] - 8:13 argument [6] - 5:21, 10:18, 10:21, 12:23, 16:11, 16:13 arose [2] - 10:8, 10:9 Arsht [1] - 1:18 art [8] - 6:25, 8:14, 9:11, 10:7, 12:13, 12:14, 12:19, 17:7 aside [1] - 3:14 asserting [1] - 8:4 assertions [1] - 5:22 attorney [1] - 16:19 availability [1] - 21:9 available [4] - 16:10, 16:12, 18:10, 21:22 AVENTIS [1] - 1:4	B barring [1] - 3:10 based [4] - 6:24, 9:10, 9:11, 16:20 BEFORE [1] - 1:14 begin [1] - 3:16 behalf [1] - 14:6 Bell [6] - 5:4, 5:7, 5:14, 6:3, 6:11 Bell's [1] - 6:16 Bench [2] - 3:9, 15:20 better [1] - 17:11 Bill [1] - 2:18 biotechnology [1] - 17:8 bit [3] - 3:4, 7:2, 7:3 Blumenfeld [8] - 2:12, 3:25, 8:9, 9:6, 10:23, 12:7, 13:3, 14:8 BLUMENFELD [13] - 1:17, 2:11, 3:17, 4:4, 6:9, 9:7, 10:25, 12:9, 13:4, 13:20, 16:14, 19:20, 20:5 body [1] - 19:21 box [1] - 19:10 brevity [1] - 20:16 brief [1] - 8:8 briefs [1] - 12:2 brought [1] - 15:25 busy [1] - 21:19	circumstances [2] - 8:23, 10:24 cite [1] - 19:4 Civil [1] - 1:4 Claim [7] - 6:23, 9:9, 9:10, 9:14, 9:15, 10:1, 10:2 claim [2] - 6:23, 9:10 claimed [2] - 8:16, 10:8 claims [1] - 8:16 classic [1] - 15:8 clear [2] - 7:12, 11:19 clinician [5] - 5:5, 6:4, 6:5, 8:18, 21:18 closings [2] - 20:19, 20:25 coin [1] - 14:9 colleague [1] - 10:23 comfortable [5] - 20:3, 20:4, 20:9, 21:25, 22:4 coming [1] - 12:18 comment [1] - 21:3 commercial [11] - 5:9, 6:2, 6:15, 7:2, 7:13, 9:14, 9:25, 10:10, 10:13, 11:7, 12:17 complains [1] - 13:1 completed [1] - 10:16 completely [1] - 20:23 complicated [1] - 15:21 complied [2] - 16:3, 16:6 comply [1] - 16:8 compound [2] - 8:16, 10:11 concern [1] - 11:25 concluded [1] - 22:14 conclusions [1] - 6:20 Conference [2] - 1:12, 22:14 consideration [1] - 7:21 considerations [11] - 5:6, 7:1, 7:6, 7:13, 7:17, 8:10, 9:3, 9:9, 11:5, 21:12 considered [1] - 8:1 considering [1] - 7:24 consistent [1] - 15:12 contesting [1] - 16:8 context [7] - 8:20, 9:2, 13:12, 14:4, 14:21, 17:2, 18:12 contexts [1] - 8:12 continuation [1] - 15:14 continuations [1] -	16:9 CONTINUED [1] - 2:1 convenience [1] - 22:7 conversations [1] - 4:6 core [1] - 17:4 correct [1] - 13:3 Counsel [2] - 1:22, 2:7 counsel [10] - 2:9, 2:20, 10:4, 11:9, 11:13, 12:3, 20:3, 20:12, 21:16, 22:13 counterpart [1] - 6:4 couple [1] - 9:18 course [2] - 3:2, 3:5 Court [6] - 7:25, 11:21, 14:12, 17:1, 17:11 COURT [38] - 1:1, 2:9, 2:15, 2:20, 3:23, 4:2, 4:18, 5:13, 6:6, 6:8, 8:8, 9:5, 10:4, 10:22, 11:9, 12:6, 12:21, 12:25, 13:16, 14:5, 15:5, 16:16, 17:24, 18:13, 18:18, 18:22, 19:9, 19:16, 19:19, 20:2, 20:7, 20:11, 20:15, 21:13, 21:16, 21:25, 22:9, 22:12 Court's [1] - 20:23 cover [2] - 4:7, 19:24 COY [1] - 2:4
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